

NEWS RELEASE

Kazia Therapeutics Announces Presentation of EVT801 Clinical Data at 15th Biennial Ovarian Cancer Research Symposium

2024-09-23

SYDNEY, Sept. 23, 2024 /PRNewswire/ -- Kazia Therapeutics Limited (NASDAQ: KZIA), an oncology-focused drug development company, is pleased to announce the presentation of data highlighting promising clinical activity of EVT801 in high grade serous (HGS) Ovarian Cancer at the 15th Biennial Ovarian Cancer Research Symposium, co-presented by American Association of Cancer Research (AACR) and the Rivkin Center for Ovarian Cancer Research on Saturday, September 21, 2024 in Seattle Washington.

Dr. John Friend, CEO Kazia Therapeutics presented preliminary data from a Phase 1 first-in-human clinical trial evaluating the safety and tolerability of EVT801, a highly selective small molecule VEGFR3 inhibitor targeting tumour angiogenesis. The Phase 1 study met its primary objectives, with the maximal tolerated dose identified at 500mg twice a day (BID). The Phase 1 study also identified the recommended Phase 2 dose starting at 400mg BID. It was observed that EVT801 was tolerated across all doses, with the majority of toxicities being mild to moderate and transient in nature.

Key points of the presentation included:

- A total of 26 patients were treated across 6 dosing cohorts ranging from 50mg once daily (QD) to 500mg twice daily (BID)
- Patients with eleven different cancer types (ex. colon, renal cell, pancreatic) were enrolled in the study, with heavily pretreated advanced ovarian cancer being the most prevalent indication (11 patients)

- Biomarkers have shown strong VEGFR3 expression in multiple indications, including ovarian cancer
- Encouraging clinical activity in High Grade Serous ovarian cancer patients with forty-six percent (46%) having stable disease or for at least three cycles, including two patients who received 9 cycles
- One patient had a partial response (-39% decrease) after 2 cycles of EVT801 therapy

Dr John Friend, CEO of Kazia Therapeutics, commented: "I was honored to participate at the Ovarian Cancer Research Symposium and present our findings to fellow clinicians and ovarian cancer researchers from around the globe. Ovarian cancer is often diagnosed at late stages with poor patient prognosis, so the data from the Phase 1 study is extremely encouraging and gives us confidence that we could potentially have a first-in-class VEGFR-3 inhibitor with EVT801."

Abstract: Phase I study of EVT801, a VEGFR-3 inhibitor, shows promising clinical activity in HGS ovarian cancer

<https://www.xcdsystem.com/rivkin/program/ZR7NvO4/index.cfm?pgid=1697>

September 21, 2024 – 11:30am-1:30pm

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, an investigational brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat multiple forms of brain cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of ten clinical trials in this disease. A completed Phase 2 study in glioblastoma reported early signals of clinical activity in 2021, and a pivotal study in glioblastoma, GBM AGILE, has been completed with presentation of paxalisib arm data expected later in 2024 at a major medical conference. Other clinical trials involving paxalisib are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these trials having reported encouraging interim data.

Paxalisib was granted Orphan Drug Designation for glioblastoma by the FDA in February 2018, and Fast Track Designation (FTD) for glioblastoma by the FDA in August 2020. Paxalisib was also granted FTD in July 2023 for the treatment of solid tumour brain metastases harboring PI3K pathway mutations in combination with radiation therapy. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA for diffuse intrinsic pontine glioma in August 2020, and for atypical teratoid / rhabdoid tumours in June 2022 and July 2022, respectively.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April

2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided evidence of synergy with immuno-oncology agents. A Phase I study has been completed and preliminary data was presented at 15th Biennial Ovarian Cancer Research Symposium in September 2024.

For more information, please visit www.kaziatherapeutics.com or follow us on X @KaziaTx.

Forward-Looking Statements

This announcement may contain forward-looking statements, which can generally be identified as such by the use of words such as "may," "will," "estimate," "future," "forward," "anticipate," or other similar words. Any statement describing Kazia's future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for results and data related to Kazia's clinical and preclinical trials, Kazia's strategy and plans with respect to its programs, including paxalisib and EVT801, the potential benefits of EVT801 as a VEGFR3 inhibitor and the potential market opportunity for EVT801. Such statements are based on Kazia's current expectations and projections about future events and future trends affecting its business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including risks and uncertainties: associated with clinical and preclinical trials and product development, related to regulatory approvals, and related to the impact of global economic conditions. These and other risks and uncertainties are described more fully in Kazia's Annual Report, filed on form 20-F with the SEC, and in subsequent filings with the United States Securities and Exchange Commission. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this announcement.

This announcement was authorized for release by Dr John Friend, CEO.

View original content to download multimedia:<https://www.prnewswire.com/news-releases/kazia-therapeutics-announces-presentation-of-evt801-clinical-data-at-15th-biennial-ovarian-cancer-research-symposium-302255558.html>

SOURCE Kazia Therapeutics Limited